Q-Code Q3A Quality Requirements

For Labels used in Medical products

The following are the quality requirements for product purchased under Q-code Q3A. Please reference the Plexus Supplier Quality Manual DCS 10503 for additional details and purchasing requirements. Unless a written waiver is received from Plexus, the supplier agrees to abide by the quality requirements listed below.

1st Shipment/EC changes - The documentation and quality requirements for the initial shipment and/or the first shipment after any changes have been made, are as follows:

A. First Article Inspection Report (FAIR) - All dimensions must be within print tolerance. Any dimension which is not within print specification must be approved by Plexus in writing before product can be shipped. The Label used for the FAIR must be identified as such and attached to the COC as a sample with the shipment. The requirement is not applicable for standard or catalog labels (specifications not defined by Plexus or Customer documentation).

B. Certificate of Compliance – Must be titled as such and include a statement of compliance to all applicable specifications (statement is not required to list, but shall cover all the applicable specifications such as drawing, PO, customer specifications, Plexus G9000-3, NFS, IPC specifications, UL, etc.). It also must include the following information for traceability:

- Name of Supplier (if different than the actual Manufacturer/OEM/OCM)
- Plexus part number ordered on the Plexus PO
- EC level or Revision level as specified on the Plexus PO for the Plexus part number ordered
- Quantity Shipped
- Plexus PO number
- Name of Manufacturer/OEM/OCM
- Manufacturer's/OEM's/OCM's Part Number
- The Manufacturer/OEM/OCM Lot numbers **or** Date Codes (both are preferred) for each shipment
- Location or place of manufacture
- If the product has a shelf life, the manufacturer or cure date, batch number, the shelf life and expiration date must be included (note: the remaining shelf life must be greater than 50% of the stated shelf life). Any special handling and/or storage requirements must also be included
- Name and title of supplier representative certifying the product

C. Material Certification - This must list all materials used in the product (i.e. label material, adhesive, printing ink, etc.)

All cartons, required documentation, labels, packaging and packing slips must have the Plexus part number, EC level or revision (if applicable), date code(s), quantity, and P.O. number listed on them.

All Shipments - The documentation and quality requirements as listed below are required with each shipment

A. One Sample Label From Each Lot - One **sample** label (not to be included in the packing list or invoice quantity) must be identified as such and secured to the C.O.C. An individual sample label must be sent for **each** production lot of labels included in the shipment. If the sample has previously been sent for a particular production lot, it must be stated as such on the COC referencing the shipment in which it was sent. The sample will be retained by Plexus as part of our

acceptance verification. This requirement is not applicable for standard or catalog labels (specifications not defined by Plexus or Customer documentation).

B. Certificate of Compliance. – Must be titled as such and include a statement of compliance to all applicable specifications (statement is not required to list, but shall cover all the applicable specifications such as drawing, PO, customer specifications, Plexus G9000-3, NFS, IPC specifications, UL, etc. It also must include the following information for traceability:

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- Plexus PO number
- Name of Manufacturer/OEM/OCM
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The above listed required documentation must be submitted with each shipment. Shipments received without the completion and proper execution of these Quality Requirements is considered non-conforming and Plexus reserves the right to return to the supplier at the supplier's expense.

Product Change Notification

Product or Process change notification requests (PCNs) shall be submitted to pcns@plexus.com, please reference the details of our PCN policy and requirements in the Plexus Supplier Quality Manual DCS 10503.

Revision History

REV	RELEASE DATE	ORIGINATOR	DESCRIPTION OF CHANGE(S)	REASON FOR CHANGE(S)
E	27 Mar 2020	Scott Ubl	Updated format and COC details	